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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,638	11/14/2000	Isidore Rigoutsos	YOR920000435US1	8850

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EXAMINER

LY, CHEYNE D

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 03/26/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/712,638

Applicant(s)

RIGOUTSOS ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 23, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 13-22, 24 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 23 and 25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 5.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: PTO 948 Attachment.

DETAILED ACTION

1. Applicant's election without traversal of Group I, claims 1-12, 23 and 25, in Paper No. 5, filed April 23, 2002, is acknowledged.
2. Claims 1-12, 23 and 25 are examined on the merits.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12, 23, and 25, drawn to a method of providing a set of sequences, discovering a plurality of patterns, and determining if a candidate sequence is comprised of a predetermined number of patterns, classified in class 702, subclass 20.
 - II. Claims 13-22, 24, and 26, drawn to a method for unsupervised building and exploitation of composite descriptors, classified in class 702, subclasses 19 and 27.
4. The inventions of Groups I and II are distinct inventions because they are directed to different methods regarding the critical limitations therein. For Group I, the critical feature is a method for providing a set of sequences, discovering a plurality of patterns, and determining if a candidate sequence is comprised of a predetermined number of patterns. For Group II, the critical feature is a method for unsupervised building and exploitation of composite descriptors. It is acknowledged that the commonality of the two methods is the data regarding sequences. However, the different intended goal and active steps of each method cause them to be distinct. Therefore, the completely distinct critical features of each Group support the undue search burden if they were examined together.

DRAWING

5. Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that a PTO Form 948 is mailed herewith. Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Sequence Compliance

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). See, for example, Tables 1-4. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because Tables 1-4, contain amino acid sequences with sequence lengths that are equal to or greater than 4 amino acid molecules and these sequences do not have SEQ ID Nos cited along with each sequence in the specification or Figure. Applicants are also reminded that SEQ ID Nos are not required in Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are required to submit a new computer readable form sequence listing, a paper copy for the specification, statements under 37 CFR § 1.821(f) and (g), if there is a need to list additional sequences in the listing. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to

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this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Claim Objections

7. Claim 5, line 1, is objected to because of the following informalities: Line 1 is missing a comma between the terms "of" and "if". Appropriate correction is required.

8. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (Page 43, lines 11-12). Applicant(s) is/are required to delete the embedded hyperlink and/or other form of browser-executable code, or inactivate the hyperlink.

See MPEP § 608.01.

LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for EF1G/PS50040, G protein-coupled receptors, the helix-turn-helix DNA, and C. elegans genome which have properties and features instantly disclosed, does not reasonably provide enablement for any sequence wherein there is not any knowledge about properties or features of the sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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11. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

12. It is acknowledged that Applicants provide enablement for EF1G/PS50040, G protein-coupled receptors, the helix-turn-helix DNA, and *C. elegans* genome which have properties and features instantly disclosed (Pages 25-48). However, Applicants do not reasonably provide enablement for the use the method in this instant application with any sequence wherein there is not any knowledge about the properties or features of the sequence. Consistent with the scope of claim 4, a sequence in itself is a specific property or feature of the said sequence. The specification lacks sufficient direction for one skilled in the art use the method in this instant application with any sequence wherein there is not any knowledge about the properties or features of the sequence. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the method of this instant application for a sequence to which there is no knowledge about properties or features of the said sequence without undue experimentation.

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Consistent with the scope of claim 4, a sequence in itself is a specific property or feature of the said sequence. Therefore, the specification lacks sufficient description of a sequence wherein there is not any knowledge of the properties or features of the said sequence.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17. Specific to claims 1, line 2; 4, line 2; 23, line 5; and 25, line 4, the phrase "are not aligned" causes the claim to be vague and indefinite. It is unclear what criteria are being used to determine that a set of sequences is not aligned. Is it sequence identity, similarity or merely arranging for at least one sequence to be in-line with another? Clarification of the metes and

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bounds is required. Claims 2, 3 and 5-12 are rejected due to being directly or indirectly dependent from claim 1.

18. Specific to claims 1, line 4; 2, lines 3 and 5; 5, line 2; and 25, line 7, the phrases "candidate sequence" or "patterns" cause the claim to be vague and indefinite. It is unclear what criteria are being used to determine that a sequence is a candidate sequence. Is it sequence identity, similarity or distribution? Clarification of the metes and bounds is required. Claims 3, 4 and 6-12 are rejected due to being directly or indirectly dependent from claim 1.

19. Specific to claim 6, lines 2-4, the phrase from lines 2-4 in its entirety ("some...positions.") causes the claim to be vague and indefinite due to improper English grammar. Further, the phrase "don't care" is vague and indefinite. It is unclear what criteria are being used to determine "don't care" positions. Clarification of the metes and bounds is required. Claim 7 is rejected due to being dependent from claim 6.

CLAIM REJECTIONS UNDER - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. Claims 1-8, 10-12, 23 and 25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Benson et al. (1997).

22. Benson et al. discloses GenBank contained 602, 072, 354 nucleotide bases from 920,588 different sequences (Page 1, column 2, lines 7 and 8), as in claims 4 and 6. "Unigene starts with human entries in the primate (PRI) division of GenBank, combines these with human ESTs and

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creates clusters of sequences that share virtually identical 3' untranslated regions (3'UTRs) (Page 2, column 2, lines 53-57), as in claims 2 and 7. "One of the most frequent uses of GenBank is sequence similarity searching" (Page 5, column 1, lines 41 and 42", the above disclosures anticipate the limitations of claim 1. "NCBI offers the BLAST family of search programs to perform fast searching with rigorous statistical methods for judging the significance of matches" (Page 5, column 1, lines 42-44), as in claim 3. NCBI builds GenBank primarily from the direction submission of sequence data from authors and secondarily from scanning the journal literature (Page 1, column 1, lines 13-15), as in claim 5. "WWW access to BLAST currently offers two interfaces, a 'Basic' version with default search parameters and an 'Advanced' option which allows customization of the parameters. A new graphical version called PowerBLAST, designed for rapid analysis and annotation of large contigs of genomic sequence data" (Page 5, column 1, lines 44-49). "Since the three-dimensional structure information has been linked to the set of protein sequences, users can easily determine as set of sequence neighbors for a given sequence and then locate and visualize structures for members of the neighbor set (Page 5, column 1, lines 34-40), the above disclosures anticipate the limitations of claims 8 and 10-12. "The server/client version of *Entrez* operates with a client program on a user's machine over the Internet connected to a server located at NCBI. Client programs for Macintosh, PC and UNIX computers can be obtained by downloading from 'ncbi.nlm.nih.gov' (Page 5, column 1, lines 26-30), the above disclosures anticipate the limitations of claims 23 and 25.

CONCLUSION

23. NO CLAIM IS ALLOWED.

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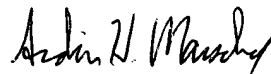
24. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

27. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
3/24/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER